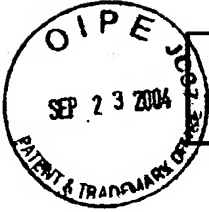


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CASE PR/4-30843D



FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV540156543 US

Express Mail Label Number

September 23, 2004

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 1617

HASSAN ET AL.

Examiner: Hui, San-ming

APPLICATION NO: 10/718,316

FILED: NOVEMBER 20, 2003

FOR: COMBINATIONS OF FORMOTEROL AND MOMETASONE  
FUROATE FOR ASTHMA

**MS: Amendment**

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

AMENDMENT

Sir:

This Reply is submitted to the Office Action mailed June 25, 2004. Reconsideration of the present rejections and withdrawal of the present rejections are respectfully requested.

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express 20- } 18.00

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Office Action in Serial No. 09/942,805 shows a synergistic anti-inflammatory effect for a combination of particular doses of formoterol and mometasone.

The Declaration of Dr. Trifilieff submitted herewith shows a synergistic effect for a combination of formoterol and mometasone over a different, much wider range of doses, with dose ratios of formoterol to mometasone ranging from 1:2 to 1:100. This Declaration relates to comparative tests in an animal model measuring bronchoconstriction following antigen challenge, the test results showing the comparative effects of formoterol, mometasone and combinations of formoterol and mometasone in reducing the bronchoconstriction induced by the antigen, i.e. the comparative effects in improving lung function. The results show a considerable synergistic effect for the combination of formoterol and mometasone, for all doses of formoterol and mometasone used.


Also, the Examiner suggests that the claims are not limited to the synergistic amount of formoterol and mometasone as supported by the animal data. The only meaningful way to correlate the synergistic amount of formoterol and mometasone between humans and the animal test data in the present application is clinically which, as the Examiner can well appreciate, is prohibitively expensive, time-consuming and quite restrictive. It would therefore be unreasonable to require that clinical trials are conducted to correlate any synergistic amount between human models and animal models. It is therefore Applicant's conviction that the unexpected results of the combination of formoterol and mometasone as described in the Declaration of Dr. Trifilieff and supported by the application supports the claims now pending.

Based on the foregoing, Applicants respectfully request that the 35 U.S.C. §103(a) rejection be reconsidered and withdrawn with respect to claims 1-20.

In view of the remarks and the amendments, further and favorable consideration of the present application and the allowance of all pending claims are respectfully requested. The Examiner is also invited to contact the undersigned should the Examiner believe that such contact would expedite prosecution of the present application.

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 430  
East Hanover, NJ 07936-1080  
(862) 778-2614

Respectfully submitted,

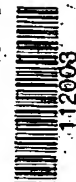
  
Gregory C. Houghton  
Attorney for Applicants  
Reg. No. 47,666

Date: 9/23/04

Docket Number 4-30843C	
FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10	
EL997254610US	November 20, 2003
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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

16834 U.S. PTO  
10/718316



## UTILITY PATENT APPLICATION TRANSMITTAL AND FEE SHEET

Transmitted herewith for filing under 37 CFR §1.53(b)(1) is a continuation of prior Application No. 10/262,408, filed October 1, 2002.

Applicant (or identifier): HASSAN ET AL.

Title: COMBINATIONS OF FORMOTEROL AND MOMETASONE  
FUROATE FOR ASTHMA

Enclosed are:

1. ☒ Specification (Including Claims and Abstract) - 22 pages
2. ☐ Drawings - sheets
3. Declaration and Power of Attorney
  - a. ☐ Newly executed (original or copy)
  - b. ☒ Copy from a prior application (signed or with indication that original was signed)
    - i. ☐ Deletion of Inventors  
Signed statement attached deleting inventor(s) named in the prior application
4. ☒ Incorporation By Reference  
The entire disclosure of the prior application, from which a copy of the Declaration and Power of Attorney is supplied under Box 3b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
5. ☐ Microfiche Computer Program (appendix)
6. Nucleotide and/or Amino Acid Sequence Submission
  - ☐ Computer Readable Copy
  - ☐ Paper Copy
  - ☐ Statement Verifying Identity of Above Copies
7. ☒ Preliminary Amendment
8. ☐ Assignment Papers (Cover Sheet & Document(s))
9. ☐ English Translation of
10. ☐ Information Disclosure Statement
11. ☐ Certified Copy of Priority Document(s)
12. ☒ Return Receipt Postcard
13. ☒ Other: Application Data Sheet, Claim of Priority Under USC §119

☒ The right to elect an invention or species that is different from that elected in parent Application No. 10/262,408 in the event of a restriction or election of species requirement that is identical or substantially similar to that made in said parent application is hereby reserved.

Filing fee calculation:

☒ Before calculating the filing fee, please enter the enclosed Preliminary Amendment.

#1302  
Charged:  
1 add'l claim } 18.00  
= in excess 20 }

☐ Before calculating the filing fee, please cancel claims

Basic Filing Fee							\$	770
Multiple Dependent Claim Fee (\$ 290)							\$	
Foreign Language Surcharge (\$ 900)							\$	
	For	Number Filed		Number Extra		Rate		
Extra Claims	Total Claims	20	-20	0	x	\$ 18	=	\$
	Independent Claims	1	-3	0	x	\$ 86	=	\$
TOTAL FILING FEE							\$	770

- ☒ Please charge Deposit Account No. 19-0134 in the name of Novartis in the amount of \$770. An additional copy of this paper is enclosed. The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.16 and §1.17 which may be required in connection with this application, or credit any overpayment, to Deposit Account No. 19-0134 in the name of Novartis.

Please address all correspondence to the address associated with Customer No. 001095, which is currently:

Thomas Hoxie  
Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 430  
East Hanover, NJ 07936-1080

Please direct all telephone calls to the undersigned at the number given below and all telefaxes to (973) 781-8064.

Respectfully submitted,



D. Gabrielle Brouillette  
Agent for Applicants  
Reg. No. 51,384  
Tel. No. (862) 778-7809

Date: November 20, 2003